

(CLIA WAIVED)

## Identify® Diagnostics

### Drug Test Cups

#### Test Instruction/ Questions & Answers

(Information for the OTC users and for health care professional users)

#### What are Identify® Diagnostics Drug Test Cups ?

Identify® Diagnostics Drug Test cups is a urine drug screening test, and if needed, a confirmation service. It provides preliminary urine screening results for the detection/ presence of the following drugs of abuse: Amphetamine, Cocaine, Buprenorphine, Methamphetamine, Ecstasy (MDMA), Opiates, Opiates300, Phencyclidine, Marijuana (THC), Benzodiazepines, Methadone, Barbiturates, Tricyclic Antidepressants , Propoxyphene and Oxycodone. The test detects any or all of these drugs when they are above the detection limit of the test. The test is intended for over-the-counter (OTC) users and for health care professional users.

#### What is the Cut-off level and approximate detection time?

Drug (Identifier)	Cut-off Level	Minimum detection time	Maximum Detection time
Amphetamine (AMP)	1000 ng/mL	2 – 7 hours	2 – 4 days
Cocaine (COC)	300 ng/mL	1 – 4 hours	2 – 4 days
Buprenorphine (BUP)	10 ng/mL	2 – 4 hours	2 – 6 days
Methamphetamine (MET/mAMP)	1000 ng/mL	2 – 7 hours	2 – 4 days
Ecstasy (MDMA)	500 ng/mL	2 – 7 hours	2 – 4 days
Opiates (OPI)	2000 ng/mL	2 hours	2 – 3 days
Opiates 300 (MOP)	300 ng/mL	2 hours	2 – 3 days
Phencyclidine (PCP)	25 ng/mL	4 – 6 hours	7 – 14 days
Marijuana (THC)	50 ng/mL	2 hours	Up to 40+ days
Benzodiazepine (BZO)	300 ng/mL	2 – 7 hours	1 – 4 days
Methadone (MTD)	300 ng/mL	3 – 8 hours	1 – 3 days
Barbiturates (BAR)	300 ng/mL	2 – 4 hours	1 – 3 weeks
Tricyclic Antidepressants (TCA)	1000 ng/mL	8 – 12 hours	2 – 7 days
Propoxyphene (PPX)	300 ng/mL	1 – 6 hours	7 – 10 days
Oxycodone (OXY)	100 ng/mL	1 – 3 hours	1 – 2 days

The Identify® Diagnostics Drug Test cups may not detect the amount of drugs in a urine sample that are below the cut-off level. Even though some level of drug may be present in a urine sample, the sample would still be considered a Negative Result if the drug level is below the cut-off level.

#### When is the best time to collect a sample?

The sample should be collected as soon as possible after suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. This is because each drug is cleared by the body and is detected in the urine at different times and rates.

#### How much sample do I need?

Fill the Drug Test Cup with urine to at least the minimum fill level line, which is approximately 30 mL, then fill the sample Vial to two-thirds (2/3) full.

#### How do I perform a test with the Identify® Diagnostics Drug Test Cups?

- 1) Begin in a well-lit place. Have a watch or timer ready.
- 2) Make sure the urine sample and the Drug Test Cup is at room temperature before testing only if the sample was refrigerated after collection.
- 3) Open the foil pouch at the notch and remove the Drug Test Cup.

4) Remove the cap from the Drug Test Cup.

5) Fill the Drug Test Cup with urine to at least the minimum fill level line, which is approximately about 30 mL, it is OK to have some extra urine sample, wipe off any splashes or spills on the outside of this cup.

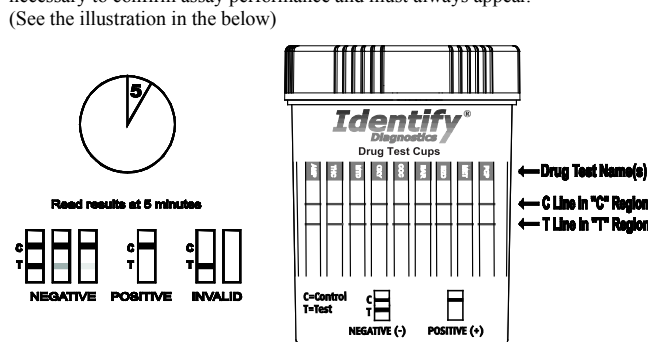
6) Place the test cup on a flat dry surface. Start the timer and wait for the colored line(s) to appear.

7) Read the test result(s) at 5 minutes.

**NEGATIVE RESULTS:** A negative result is indicated by two colored lines (of any intensity): one in the control region “C” AND one in the test region “T”. This result means that the urine screened negative. **(REMEMBER-EVEN A VERY FAINT LINE IS A NEGATIVE RESULT)**

**PRELIMINARY POSITIVE RESULTS:** A single colored line which appears in the control region “C” and NO line in the test region “T” means the urine screen is considered to be **PRELIMINARY POSITIVE**. The urine sample must be sent to a laboratory for further testing. More than one test may be “preliminary positive.”

**INVALID RESULT:** A test should be considered Invalid Result if no lines appear or if a line appears in the test region “T” without a line in the control region “C”. The presence of a colored line in the control region “C” is necessary to confirm assay performance and must always appear. (See the illustration in the below)



#### What does a negative test result mean?

This means that if the sample was collected properly, and if the test was performed according to direction, then the drug or its metabolite level is below the detectable level. However, if drug use is still suspected, you may wish to re-screen at a later time.

#### What does a preliminary positive test result mean?

This means that the test has reacted with something in the sample and must be sent to the lab for a more accurate test. Please review the Test Limitations following this section. First, and most important: BE PATIENT. The result you obtained is called preliminary for a reason. The sample MUST be tested by the clinical laboratory in order to determine if a drug of abuse is actually present. You will never know for sure without taking the second step.

#### Remember, drug screening test is the first step in a two step process:

- Step 1: Screen out (eliminate) the negative samples.
- Step 2: Send any sample which does not give a negative result to a laboratory for further testing.

#### Test Limitations:

1. Failure to use this kit as directed may result in an insufficient sample or an inaccurate screening result.

2. This test can be used on urine samples only. No other fluids have been evaluated. **DO NOT** use this device to test anything but urine.

3. The laboratories must receive an adequate amount of sample to perform confirmation testing.

☒ The urine sample is perishable. Old urine samples may not be suitable for testing.

☒ Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result.

4. The possibility exists that substances and factors not described in this instruction may interfere with the test, causing false results (e.g. technical or procedural error).

☒ Adulterated urine samples may produce erroneous results.

☒ Strong oxidizing agents such as bleach can oxidize drug analytes. If a sample is suspected of being tampered with, a new sample must be obtained.

☒ This test provides a screening result. It is not designed to determine the actual concentration of a drug or the level of intoxication.

☒ Liability is limited to the purchase price of the kit.

#### Mailing a Urine Sample to a Laboratory for Confidential Confirmation Testing

If you get a preliminary positive result, you need to send the sample to a certified Laboratory for confirmation test as soon as possible. If you have obtained a Confirmation Kit from your supplier, the kit includes a sample Vial, a Confirmation Test Label, a specimen bag and pre-addressed mailing box, the following steps are for its use:

1. Ensure that the sample Vial is about two thirds (2/3) full with the sample and the cap is tightly closed.

2. Fill out the Confirmation Test Label for the lab:

a) Identify the drug that tested positive on the label. For example, if the screening test indicated the THC was positive, mark an “X” next to the THC test.

b) Fill in the blank in “Sample Collection Date” \_\_\_\_\_

3. Keep the top portion of the label that contains the Identification number and 1-800 toll free telephone number for your record, you will need it to obtain the results.

4. Place the Confirmation Test Label onto the side of the vial.

5. Place the sample Vial into the specimen bag and seal the specimen bag.

6. Place the sealed specimen bag into the pre-addressed mailing box. Close the mailing box. **(PLEASE NOTE THAT THE MAILING BOX IS NOT PRE-PAID. YOU MUST ATTACH THE PROPER POSTAGE TO HAVE A CARRIER SERVICE DELIVER IT.)**

7. Place the mailing box in any US Postal Service Office.

**(IT IS IMPORTANT TO MAIL IT RIGHT AWAY! Old urine samples may not be suitable for testing.)**

8. Normally you can get the test results in 5 to 10 business days. Dial 1-800 toll free telephone number listed in the top portion of the label, and identify yourself with the Identification number to receive the test result.

9. Test results will be kept on file for thirty (30) days. So you must call within thirty (30) day period to receive your test results. Remember to have your identification number handy when you call. Results will not be disclosed without an ID number.

#### The following is common street names for some commonly abused drugs:

Drug	Identifier	Street Name
Amphetamine	AMP	Speed, amp, bennie, chalk, black beauties
Cocaine	COC	Big C, coke, snow, flake, candy, crack, blow, rock
Buprenorphine	BUP	Bupe, subs, subbies, orange guys

Methamphetamine	MET	Crystal, meth, ice, glass
Ecstasy	MDMA	Ecstasy, E Adam, XTC, X
Opiates	OPI	Heroin, H, hairy hombre, horse, jones, scag
Opiates 300	MOP	-----
Phencyclidine	PCP	Angel dust, magic dust, sherms, star dust
Marijuana	THC	Pot, weed, herb, bud, MJ, doobie, reefer, grass joint, homegrown, spliff
Benzodiazepine	BZO	Downers, tranks, benzos
Methadone	MTD	Done, fizzies, chocolate chip cookies, joice, wafer
Barbiturates	BAR	Barbs, birds, red devils, yellow jackets, block busters
Tricyclic Antidepressants	TCA	-----
Propoxyphene	PPX	Pinks, footballs, pink footballs, yellow footballs, 65's and N's
Oxycodone	OXY	Oxy, killers, OC, oxycotton

### What do the laboratory results mean?

- You will be told if the laboratory test result for your urine sample was positive or negative according to confirmation testing.
- The results you receive will come from the tests performed by laboratory professionals. These tests are run on very accurate and reliable equipment.
- Positive results are released only when the sample is confirmed to be positive using sophisticated techniques and equipment such as gas chromatography/mass spectrometry.
- Samples which are screened as negative do not require the second (confirmation) test. ***This can mean several things:***
  - These drugs were used in the past few days prior to providing the urine sample. Therefore, the person either doesn't do drugs or had not done them just prior to testing.
  - The person may only use a small amount of a drug, an amount too small to be detected by the test.
  - A person may take a drug that cannot be detected by Identify™ - Home Drug Testing Device Test Cups. Identify™ - Home Drug Testing Device Test Cups can only test thirteen (13) drugs and so if any other drugs were in use the test result would be negative.
  - The sample may have been tampered with or be unsuitable due to some rare technical interference.
- Certain foods and medicines may cause a positive test result.
  - People can test positive for THC (or marijuana) if they have been continually near to very heavy marijuana smoke for long periods of time even though they did not eat or smoke marijuana themselves.
  - Preliminary positive tests may arise from the cross-reactions with other substances.
- Remember, when a drug is found in the urine, testing
  - does not tell us how the drug got there (eaten, inhaled, smoked or injected)
  - does not distinguish a prescription medicine from a drug of abuse.
  - does not tell if the positive result is from a food that someone ate.
- In the event a positive result for a drug was confirmed, please consult with a proper counselor who can help you. It is important that you remain calm and do not react in a negative way to the situation.
- If you have received a positive result and you do not believe the test result, please consult with your physician. They will review your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

### What about False Positive Results?

A screening test can give a false positive result. Certain cross reactive

substances are known to occur. These can be present due to diet, prescription medicines, over-the-counter medications, etc. This is why it is important to send any sample not giving a negative result to the laboratory for further evaluation.

Analysis by the laboratory, which involves confirmation testing, will determine whether or not a drug is present in the urine. If the laboratory reports a positive result you may be assured that the drug was indeed present. However, it would be incorrect to assume the urine sample came from a drug abuser just because the result is positive. It is necessary to determine how contact with drug occurred.

### Can False Negative Results Occur?

If you have observed behavioral changes which you feel could be caused by drug abuse, don't discard the suspicion just because the test result is reported negative. A false negative result can occur for a number of reasons. Certain products are being marketed as a means of defeating drug testing. These interfere with various methods used in either the screening or confirmation tests. Often, the concentration of the drugs in the urine sample is below the cut-off, or sensitivity, of the screening assay. When this occurs, the test is reported negative.

(The Following Technical Information and Additional Information for Health Care Professionals)

### Performance Characteristics

The consumer study was conducted among 110 lay users who had no previous experience using drug testing products. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). Pure drugs or drug metabolites were spiked into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. All incorrect results were obtained at drug concentrations between 50% to 150% cutoff levels. The test results by the lay users are summarized as below:

Drug Names	Cut-off (ng/mL)	#Test	Result Interpretation		Total Agreement with GC/MS
			Correct	Incorrect	
AMP	1000	228	226	2	99.1%
COC	300	228	223	5	97.8%
BUP	10	228	224	4	98.2%
MET	1000	228	224	4	98.2%
MDMA	500	228	221	7	96.9%
OPI	2000	228	222	6	97.4%
OPI 300	300	228	222	6	97.4%
PCP	25	228	225	3	98.7%
THC	50	228	224	4	98.2%
BZO	300	228	224	4	98.2%
MTD	300	228	226	2	99.1%
BAR	300	228	223	5	97.8%
TCA	1000	228	224	4	98.2%
PPX	300	228	225	3	98.7%
OXY	100	228	222	6	97.4%

### Quality Control

Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new device.

External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

Manufactured for:  
Medical Distribution Group Inc.  
2361 Whitfield Park Ave, Sarasota, FL 34243

## Drug Tests (Strip/Card/Cassette/Cup)

Package Insert for testing of any combination of the following drugs:  
AMP/BAR/BZO/BUP/COG/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA

Available with Specimen Validity Tests (S.V.T.) for:

Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine

*One step, rapid screening tests for the qualitative detection of drug(s) and drug metabolite(s) in human urine.*

*For in vitro diagnostic use only.*

### INTENDED USE

**Drug Tests (Strip/Card/Cassette/Cup)** is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
Amphetamine/AMP 1000	D-Amphetamine	1000 ng/mL
Amphetamine/AMP 300	D-Amphetamine	300 ng/mL
Barbiturates/BAR	Secobarbital	300 ng/mL
Benzodiazepines/BZO	Oxazepam	300 ng/mL
Buprenorphine/BUP	Buprenorphine	10 ng/mL
Cocaine/COC 300	Benzoylcegonine	300 ng/mL
Cocaine/COC 150	Benzoylcegonine	150 ng/mL
Marijuana/THC	Delta-9-THC-COOH	50 ng/mL
Methadone/MTD	Methadone	300 ng/mL
Methamphetamine/mAMP 1000/MET 1000	D-Methamphetamine	1000 ng/mL
Methamphetamine/mAMP 500/MET 500	D-Methamphetamine	500 ng/mL
Methylenedioxyamphetamine/MDMA	MDMA	500 ng/mL
Opiates 300/ Morphine/MOP/MOR/OPI 300	Morphine	300 ng/mL
Opiates 2000/OPI 2000	Morphine	2000 ng/mL
Oxycodone/OXY	Oxycodone	100 ng/mL
Phencyclidine/PCP	Phencyclidine	25 ng/mL
Propoxyphene/PPX	Propoxyphene	300 ng/mL
Tricyclic Antidepressants/TCA	Nortriptyline	1000 ng/mL

**Drug Tests (Strip/Card/Cassette/Cup)** provides only a preliminary analytical test result. The test is not intended to be used in monitoring the drug levels. A more specific alternate method must be used in order to confirm the test result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are obtained.

### SUMMARY AND EXPLANATION OF THE TEST

**Drug Tests (Strip/Card/Cassette/Cup)** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine. **Drug Tests (Strip/Card/Cassette/Cup)** optionally includes an adulteration strip for testing Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine.

### AMPHETAMINE / AMP 1000

Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and overall feeling of well-being. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in higher tolerance levels and physiological dependency leading to substance abuse. The effect of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when Amphetamines in urine exceed 1000 ng/mL, which is the suggested screening cut-off for positive specimens by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

### AMPHETAMINE / AMP 300

**Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when Amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE / AMP 1000 for summary.

### BARBITURATES / BAR

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well

being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when secobarbital in urine exceeds 300 ng/mL.

### BENZODIAZEPINES / BZO

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when oxazepam in urine exceeds 300 ng/mL.

### BUPRENORPHINE / BUP

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when Buprenorphine in urine exceeds 10 ng/mL.

### COCAINE / COC 300

Cocaine is an alkaloid present in Coca leaves (Erythroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, Cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the urine primarily as Benzoylcegonine, which can generally be detected for 24 – 48 hours after cocaine exposure. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the Cocaine metabolite in urine exceeds 300 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

### COCAINE / COC 150

**Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the Cocaine metabolite in urine exceeds 150 ng/mL. See COCAINE / COC 300 for summary.

### MARIJUANA / THC

THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the urine is 11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$ -THC-COOH), which is found in the urine within hours of exposure and remains detectable for 3-10 days after smoking. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

### METHADONE / MTD

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, Morphine). It is administered either orally, or by intravenous or intra-muscular injection. The duration of

effect of methadone is 12-24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3, 3-diphenylpyrrolidine). **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Methadone in urine exceeds 300 ng/mL.

### METHAMPHETAMINE / mAMP 1000 / MET 1000

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of methamphetamine are greater. Methamphetamine can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10 to 20 % of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Methamphetamine in urine exceeds 1000 ng/mL.

### METHAMPHETAMINE / mAMP 500 / MET 500

**Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE / mAMP 1000 for summary.

### METHYLENEDIOXYMETHAMPHETAMINE / MDMA

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartoning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2-3 hours. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of MDMA in urine exceeds 500 ng/mL.

### OPIATES 300 / MOP / MOR / OPI 300

Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Opiates in urine exceeds 300 ng/mL.

### OPIATES 2000 / OPI 2000

**Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Opiates in urine exceeds 2000 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA). See OPIATES 300 / MOP for summary.

### OXYCODONE / OXY

Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Oxycodone in urine exceeds 100 ng/mL.

### PHENCYCLIDINE / PCP

Phencyclidine, commonly known as PCP or "angel dust" is used primarily as recreational drug due to its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects

of PCP are very much dose related. Small amounts of Phencyclidines (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heat rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%). **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Phencyclidine in urine exceeds 25 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

#### PROPOXYPHENE / PPX

Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of propoxyphene level in urine exceeds 300 ng/mL.

#### TRICYCLIC ANTIDEPRESSANTS / TCA

Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs. **Drug Tests (Strip/Card/Cassette/Cup)** yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

#### S.V.T. SUMMARY

The strips contain chemically treated reagent pads, 3 to 5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to assess the integrity of the urine sample.

#### WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

- **Oxidants/PCC (Pyridinium chlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLack) is a commonly used adulterant.<sup>6</sup> Normal human urine should not contain oxidants of PCC.

- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.025. Values outside this range may be the result of specimen dilution or adulteration.

- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

- **Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.<sup>9</sup> Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.<sup>7</sup> Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.<sup>8</sup> A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an

attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

#### PRINCIPLE OF TEST

**Drug Tests (Strip/Card/Cassette/Cup)** is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test cassette, the urine specimen migrates through the test cassette by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

#### REAGENTS

**Drug Tests (Strip/Card/Cassette/Cup)** contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methyleneiodiomethamphetamine, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

#### S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants / PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

#### MATERIALS PROVIDED

- Drug Tests (Strip/Card/Cassette/Cup)
- Product insert
- Security Seal
- Procedure Card
- Adulteration color card (Optional)

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- External positive and negative controls

#### PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use after the expiration date.
3. The drug tests should remain in the sealed pouch until use.
4. All specimens should be considered potentially hazardous and handle in the same way as an infectious material.
5. All used drug tests should be discarded according to federal, state and local regulation.

#### STORAGE AND STABILITY

Store **Drug Tests (Strip/Card/Cassette/Cup)** in the sealed pouch at 2°C to 30°C. The drug tests is stable through the expiration date printed on the sealed pouch. The drug tests must remain in the sealed pouch until use. If store at 2°C to 8°C, allow the drug tests to reach room temperature (15°C to 30°C) before performing the test. Do not freeze, do not use beyond the expiration date.

#### SPECIMEN COLLECTION AND STORAGE

Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

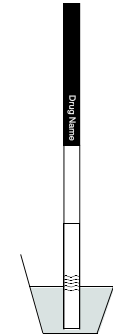
For best results, test a fresh specimen immediately following collection. Storage of specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to using.

#### TEST PROCEDURE

##### For Drug Test Strip:

**Allow the test strip, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

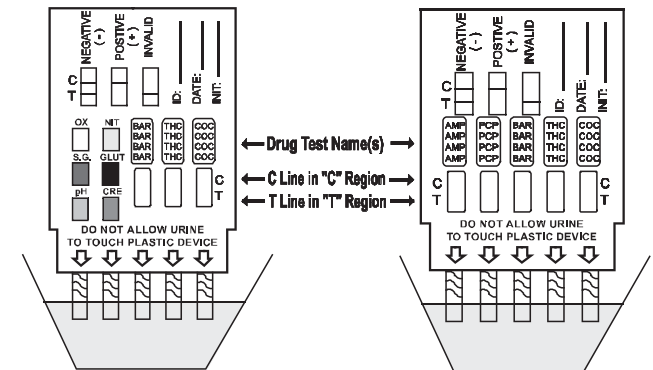
1. Remove the test strip from the sealed pouch and dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
2. Place the test strip on a flat dry surface.
3. Read the results at 5 to 10 minutes.



##### For Drug Test Card:

**Allow the test card, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

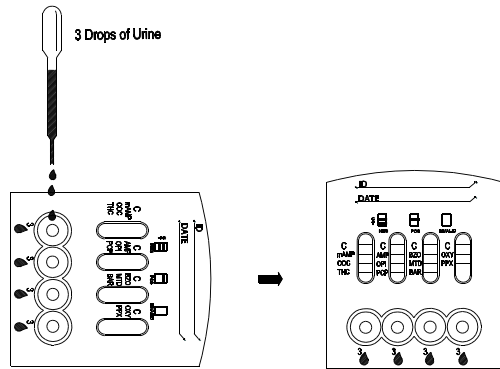
1. Remove the test card from the sealed pouch and dip the card into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip (s) of the test card just below the bottom line of the wave line on the test strips; do not dip the card above the bottom line.
2. Place the test card on a flat dry surface.
3. Read the adulteration strips between 3 to 5 minutes (when applicable) by comparing the colors in the adulteration pads to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and suggest you to retest the urine by using another specimen.
4. Read the results at 5 to 10 minutes.



##### For Drug Test Cassette:

**Allow the test cassette, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

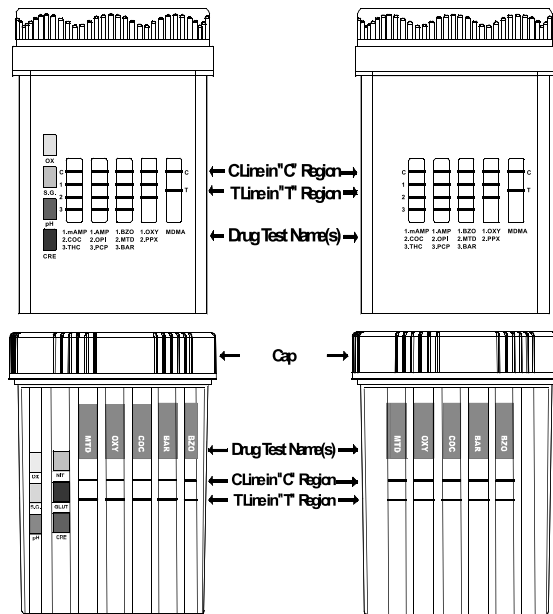
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line (s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



**For Drug Test Cup:**

Allow the cup, urine specimen (if refrigerated), and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90–100°F (33-38°C).
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.
7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.
8. Read the test results at 5 minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



**INTERPRETATION OF RESULTS**

**Positive:** One colored line appears in the Control zone (C). No line appears in the Test zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.

*Note: The samples with positive results should be confirmed with more specific method.*

**Negative:** One colored line appears in the Control zone, and another colored line appears in the Test zone. The negative result indicates the drug or its metabolite level is below the detectable level.

**Invalid:** No line appears in the Control zone. If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test cassette. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test strip or cassette. If the problem persists, discontinue using the current lot and contact your suppliers.

**ADULTERATION INTERPRETATION**

(Please refer to the color chart, if applicable)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

**QUALITY CONTROL**

1. Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new drug test.
2. External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
3. Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

**S.V.T. ADULTERATIONS LIMITATIONS**

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
5. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
6. Glutaraldehyde: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
7. Creatinine: Normal Creatinine levels are between 20 and 100 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

**LIMITATIONS**

1. Drug Tests (Strip/Card/Cassette/Cup) provides only a qualitative, preliminary testing result. A more specific testing method must be used in order to obtain a confirmed testing result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants such as bleach or other oxidizing agents may produce erroneous results. If suspected, the test should be repeated with a fresh specimen and a new drug tests.
4. The urine specimens with bacterial contamination should not be used for testing, as these contaminations may interfere with the test and cause false results.
5. A positive result does not indicate the level of intoxication, the route of the drug administration or the concentration of the drug in the urine.
6. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of test.
7. Test does not distinguish between drugs of abuse and certain medications.
8. Certain foods or food supplements may cause a false positive result.

**PERFORMANCE CHARACTERISTICS**

**Accuracy:**

The comparison studies were conducted using Drug Tests (Strip/Card/Cassette/Cup) and commercially available rapid drugs of abuse tests. The studies were performed on approximately 128 clinical specimens per drug type previous collected from the clinical settings. Presumptive positive results were confirmed by GC/MS. The following results are summarized from these comparison studies:

% Agreement with Commercial Kit									
	AMP 1000	AMP 300	BAR	BZO	BUP	COC 300	COC 150	THC	MTD
Positive Agreement	100%	100%	98%	97%	100%	100%	97.5%	100%	98%
Negative Agreement	98%	100%	98%	97%	100%	100%	97.5%	98%	97%
Total Agreement	99%	100%	98%	97%	100%	100%	97.5%	99%	97.5%

	mAMP 1000	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA
Positive Agreement	100%	100%	97%	100%	100%	98%	100%	98%	100%
Negative Agreement	98%	100%	97%	100%	100%	98%	98%	98%	98%
Total Agreement	99%	100%	97%	100%	100%	98%	99%	98%	99%

% Agreement with GC/MS									
	AMP 1000	AMP 300	BAR	BZO	BUP**	COC 300	COC 150	THC	MTD
Positive Agreement	100%	95%	98%	97%	95%	100%	100%	100%	98%
Negative Agreement	98%	100%	98%	97%	100%	100%	97.5%	98%	97%
Total Agreement	99%	97.5%	98%	97%	97.5%	100%	99%	99%	97.5%

	mAMP 1000	mAMP 500	MDMA	MOP	OPI	OXY	PCP	PPX	TCA*
Positive Agreement	100%	100%	97%	100%	100%	98%	100%	98%	100%
Negative Agreement	98%	97.5%	97%	100%	100%	98%	98%	98%	98%
Total Agreement	99%	99%	97%	100%	100%	98%	99%	98%	99%

TCA\*: TCA was based on HPLC data. BUP\*\*: BUP was based on LC/MS data.

**Sensitivity:**

Sensitivity of Drug Tests (Strip/Card/Cassette/Cup) was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug which produces at least 50% positive testing results in total numbers of determinations. The results were summarized as the following:

Drug concentration Cut-off Range	n	AMP 1000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	18	2	20	0	20	0
+25% Cut-off	20	1	19	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	BUP		COC 300		COC 150		THC	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0
+25% Cut-off	20	0	20	7	13	0	20	2	18
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MTD		mAMP 1000		mAMP 500		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0
+25% Cut-off	20	1	19	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MOP		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0

-25% Cut-off	20	20	0	13	7	20	0	20	0
+25% Cut-off	20	0	20	0	20	3	17	5	15
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	PPX			TCA		
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0		
-50% Cut-off	20	20	0	20	0		
-25% Cut-off	20	20	0	20	0		
+25% Cut-off	20	4	16	4	16		
+50% Cut-off	20	0	20	0	20		

Based on above data, sensitivity of the assay to the 18 analytes is as follows:

Amphetamine 1000:	1000 ng/mL	Methamphetamine 1000:	1000 ng/mL
Amphetamine 300:	300 ng/mL	Methamphetamine 500:	500 ng/mL
Barbiturates:	300 ng/mL	MDMA:	500 ng/mL
Benzodiazepines:	300 ng/mL	Opiates 300:	300 ng/mL
Buprenorphine:	10 ng/mL	Opiates 2000:	2000 ng/mL
Cocaine 300:	300 ng/mL	Oxycodone:	100 ng/mL
Cocaine 150:	150 ng/mL	Phencyclidine:	25 ng/mL
Marijuana:	50 ng/mL	Propoxyphene:	300 ng/mL
Methadone:	300 ng/mL	TricyclicAntidepressants:	1000 ng/mL

**Precision / Reproducibility:**

Reproducibility was determined by replicating tests on five different concentrations of each drug in urine specimens: negative, 50% below cut-off, 25% below cut-off, 25% above cut-off and 50% above cut-off. Each drug test was tested four times daily for five consecutive days with a total 20 assays at each concentration. The data are summarized below:

**Amphetamine 1000 Precision/Reproducibility Study:**

Amphetamine 1000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	1/19	95%
1500	20	0/20	100%

**Amphetamine 300 Precision/Reproducibility Study:**

Amphetamine 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	18/2	90%
375	20	0/20	100%
450	20	0/20	100%

**Barbiturates Precision/Reproducibility Study:**

Barbiturates Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

**Benzodiazepines Precision/Reproducibility Study:**

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

**Buprenorphine Precision/Reproducibility Study:**

Buprenorphine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
5	20	20/0	100%
7.5	20	20/0	100%
12.5	20	0/20	100%
15	20	0/20	100%

**Cocaine 300 Precision/Reproducibility Study:**

Cocaine 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	7/13	65%
450	20	0/20	100%

**Cocaine 150 Precision/Reproducibility Study:**

Cocaine 150 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
75	20	20/0	100%
112.5	20	20/0	100%
187.5	20	0/20	100%
225	20	0/20	100%

**Marijuana Precision/Reproducibility Study:**

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
25	20	20/0	100%
37.5	20	20/0	100%
62.5	20	2/18	90%
75	20	0/20	100%

**Methadone Precision/Reproducibility Study:**

Methadone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	1/19	95%
450	20	0/20	100%

**Methamphetamines 1000 Precision/Reproducibility Study:**

Methamphetamines 1000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	0/20	100%
1500	20	0/20	100%

**Methamphetamines 500 Precision/Reproducibility Study:**

Methamphetamines 500 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	0/20	100%
750	20	0/20	100%

**MDMA Precision/Reproducibility Study:**

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	0/20	100%
750	20	0/20	100%

**Opiates 300 Precision/Reproducibility Study:**

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

**Opiates 2000 Precision/Reproducibility Study:**

Opiates 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
1000	20	20/0	100%
1500	20	13/7	65%
2500	20	0/20	100%
3000	20	0/20	100%

**Oxycodone Precision/Reproducibility Study:**

Oxycodone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	20/0	100%
125	20	3/17	85%
150	20	0/20	100%

**Phencyclidine Precision/Reproducibility Study:**

Phencyclidine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
12.5	20	20/0	100%
18.75	20	20/0	100%

31.25	20	5/15	75%
37.5	20	0/20	100%

**Propoxyphene Precision/Reproducibility Study:**

Propoxyphene Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	4/16	80%
450	20	0/20	100%

**Tricyclic Antidepressants Precision/Reproducibility Study:**

Tricyclic Antidepressants Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	4/16	80%
1500	20	0/20	100%

The data presented here demonstrates excellent precision/ reproducibility of **Drug Tests (Strip/Card/Cassette/Cup)** across multiple concentrations of human urine.

**Analytical Specificity:**

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. Analyzing various concentration of each compound by using **Drug Tests (Strip/Card/Cassette/Cup)**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Drug Compound	Response equivalent to cutoff in ng/mL
<b>AMPHETAMINE 1000 (AMP)</b>	
D-Amphetamine	1000
D,LAmphetamine	2500
L-Amphetamine	50000
(±)3,4-Methylenedioxyamphetamine (MDA)	2000
Ephedrine	>100000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100000
<b>AMPHETAMINE 300 (AMP)</b>	
D-Amphetamine	300
D,L-Amphetamine	850
L-Amphetamine	17500
D-Methamphetamine	100000
L-Methamphetamine	>100000
(±) 3,4-Methylethylenedioxyamphetamine (MDA)	650
Ephedrine	>100000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100000
<b>BARBITURATES (BAR)</b>	
Secobarbital	300
Phenobarbital	2500
Butalbital	500
Pentobarbital	1500
Amobarbital	2500
Cyclopentobarbital	500
Butethal	800
Barbital	300
Butabarbital	1500
<b>BENZODIAZEPINES (BZO)</b>	
Oxazepam	300
Alprazolam	200
α-Hydroxylprazolam	1000
Bromazepam	250
Chlordiazepoxide	2500
Clobazam	100
Clonazepam	850
Clorazepate	250
Delorazepam	1600
Diazepam	200
Estazolam	200
Flunitrazepam	300
Lorazepam	1000
Midazolam	1500
Nitrazepam	100
Nordiazepam	400
Temazepam	150
Triazolam	500
<b>BUPRENORPHINE (BUP)</b>	
Buprenorphine	10
Norbuprenorphine	15
Buprenorphine-3-D-glucuronide	12.5
Norbuprenorphine-3-D-glucuronide	175
Morphine-3-D-glucuronide	100000
Morphine	>100000

Oxymorphone	>100000
Hydromorphone	>100000
<b>COCAINE 300 (COC)</b>	
Benzoylcegonine	300
Cocaine	>100000
Egonine HCl	35000
<b>COCAINE 150 (COC)</b>	
Benzoylcegonine	150
Cocaine	>100000
Egonine HCl	17000
<b>MARIJUANA (THC)</b>	
11-nor- $\Delta^9$ -THC-9-COOH	50
11-nor- $\Delta^8$ -THC-9-COOH	50
$\Delta^7$ -Tetrahydrocannabinol	8000
$\Delta^8$ -Tetrahydrocannabinol	10000
Cannabinol	10000
Cannabidiol	100000
<b>METHADONE (MTD)</b>	
Methadone	300
(±)-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000
Doxylamine	50000
<b>METHAMPHETAMINES 1000 (mAMP/MET)</b>	
D-Methamphetamine	1000
3,4-Methylenedioxyethylamphetamine(MDEA)	35000
(+/-)-3,4-Methylenedioxyamphetamine (MDMA)	2000
Ranitidine(Zantac)	>100000
3,4-Methylenedioxyamphetamine (MDA)	>100000
D-Amphetamine	>100000
L-Amphetamine	>100000
Ephedrine	>100000
<b>METHAMPHETAMINES 500 (mAMP/MET)</b>	
D-Methamphetamine	500
(±) 3,4-Methylenedioxyamphetamine (MDMA)	1000
Ranitidine (Zantac)	> 100000
3,4-Methylenedioxyamphetamine (MDA)	> 100000
D-Amphetamine	> 100000
L-Amphetamine	> 100000
Ephedrine	> 100000
<b>METHYLENEDIOXYMETHAMPHETAMINE (MDMA)</b>	
(+/-)-3,4-Methylenedioxyamphetamine (MDMA)	500
D-Amphetamine	>100000
L-Methamphetamine	100000
3,4-Methylenedioxyethylamphetamine (MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000
<b>OPIATE 300 (MOP/OPI 300)</b>	
Morphine	300
Codeine	300
Hydrocodone	2000
Hydromorphone	3500
Morphine 3- $\beta$ -D-glucuronide	300
6-Monoacetylmorphine	600
Normorphine	100000
Oxycodone	10000
Oxymorphone	50000
Thebaine	7000
<b>OPIATE 2000 (OPI 2000)</b>	
Morphine	2000
Codeine	2000
Hydrocodone	10000
Hydromorphone	7000
Morphine 3- $\beta$ -D-glucuronide	2000
6-Monoacetylmorphine	5000
Normorphine	100000
Oxycodone	20000
Oxymorphone	100000
Thebaine	70000
<b>OXYCODONE (OXY)</b>	
Oxycodone	100
Morphine	50000
Codeine	25000
Morphine 3- $\beta$ -D-glucuronide	50000
Hydrocodone	1600
Hydromorphone	15000
Normorphine	100000
Oxymorphone	1500
<b>PHENCYCLIDINE (PCP)</b>	
Phencyclidine	25
4-Hydroxyphencyclidine	15000
<b>PROPOXYPHENE (PPX)</b>	
Propoxyphene	300
Norpropoxyphene	7500
Methadone	> 100000
<b>TRICYCLIC ANTIDEPRESSANTS (TCA)</b>	

Notriptiline	1000
Trimipramine	4500
Amiriptryline	1000
Promazine	3000
Desipramine	1000
Imipramine	1000
Clomipramine	7500
Doxepin	3000
Maprotiline	50000

#### Interfering Compounds:

The following compounds in both drug-free urine and drug positive urines with Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamines, Mehtylenedioxyamphetamine, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, show no cross-reactivity when tested with **Drug Tests (Strip/Card/Cassette/Cup)** at a concentration of 100  $\mu$ g/mL.

#### Common Substances:

Acetaminophen	Diphenhydramine	(+/-)-Norephedrine
Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	l-Phenylephrine
Aspirin	Glucose	$\beta$ -Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Theophylline
Creatine	(+)-Naproxen	Tyramine
Dexbrompheniramine	Niacinamide	4-Dimethylaminoantipyrine
Dextromethorphan	Nicotine	(1R,2S)-(-)-N-Methyl-Ephedrine

#### Biological Materials:

Albumin	Vitamin (L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH 4.0-9.0
Hemoglobin	Urine Specific Gravity 1.003-1.025 g/mL
Glucose	

*(There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.)*

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Revised: Jan, 2025

# Identify<sup>®</sup> Diagnostics Drug Test Cups Procedure Card

**1** Remove the cap.

Cap

Peel Off Label

Urine Cup

Temperature Strip Label

Donor Name \_\_\_\_\_  
 I.D. \_\_\_\_\_  
 Date \_\_\_\_\_

READ GREEN COLOR

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

Security Seal Initials \_\_\_\_\_ Date \_\_\_\_\_

Security Seal Label

**2** Donor provides specimen and replace the cap. See reverse side for Instruction on Sealing Identify<sup>®</sup> Diagnostics Drug Test Cups.

- 3** Read urine temperature between 2-4 minutes after voiding. Normal urine temperature should fall the ranges from 90°F to 100°F.
- 4** Technician secures the cap tightly while the cup is on a flat surface, and dates and initials the security seal and places the security seal over the cap.
- 5** Technician peels off the label to view the results.

READ GREEN COLOR

90 92 94 96 98 100

Donor Name \_\_\_\_\_  
 I.D. \_\_\_\_\_  
 Date \_\_\_\_\_

READ GREEN COLOR

Identify<sup>™</sup> Diagnostics Drug Test Cups

CLIA WAIVED  
 Authorized Personnel Only  
 Peel Label to View Results

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

Identify<sup>™</sup> Diagnostics Drug Test Cups

CLIA WAIVED  
 Authorized Personnel Only  
 Peel Label to View Results

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

- 6** If adulteration test is included on the test cup, read the adulteration test results between 2-5 minutes.
- 7** Read the drug test results at 5 minutes.

2-5 minutes

See the color chart and insert for interpretation

Drug Test Name(s)

C Line in "C" Region

T Line in "T" Region

Identify<sup>™</sup> Diagnostics Drug Test Cups

Identify<sup>™</sup> Diagnostics Drug Test Cups

Identify<sup>™</sup> Diagnostics Drug Test Cups

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

C=Control T=Test

NEGATIVE (-) POSITIVE (+)

**8**

Read results at 5 minutes

5

NEGATIVE (-) POSITIVE (+) INVALID

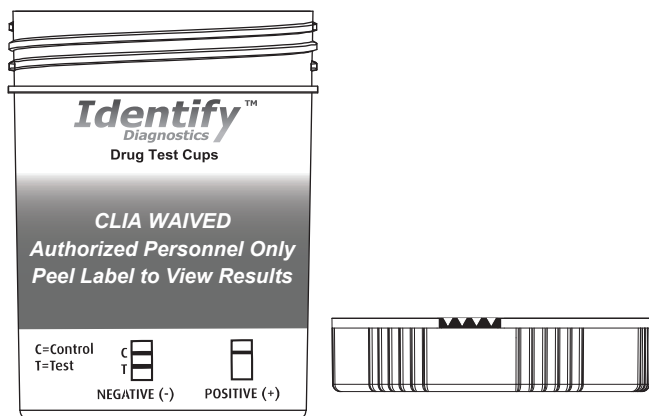
C T C T C T

All positive results are presumptive and should be confirmed by an alternative method (e.g. GC/MS)

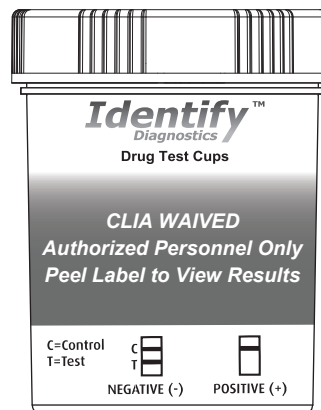
Example: Test shows positive for THC.  
 (See reverse side for Instruction On Sealing Identify<sup>®</sup> Diagnostics Drug Test Cups With The Cap)

# Instruction On Sealing Identify™ Diagnostics Drug Test Cups With The Cap

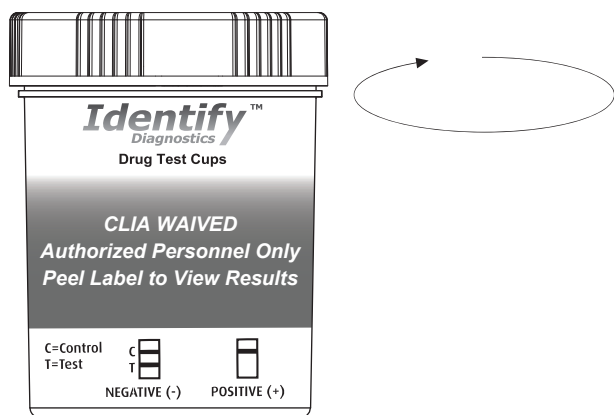
1 Pour the urine sample into the cup.



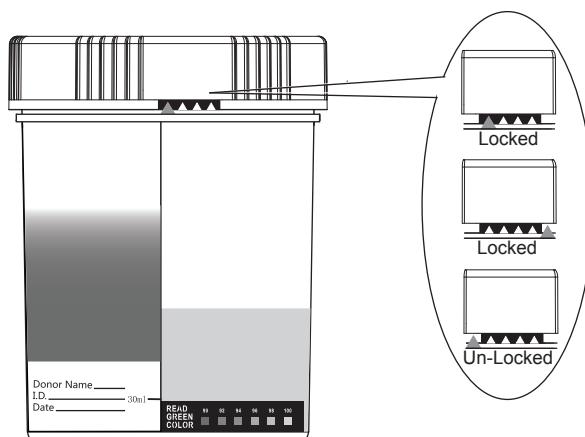
2 Place the cap flat on top of the cup.



3 Twist the cap clockwise until the lock system is locked.



4 Check to make sure the cap aligns with the top of the cup and is completely and tightly closed, and the cup is Locked. IMPORTANT: Make sure the cup MUST be locked prior to shipping to laboratory for confirmation testing. See the below pictures.



5 If the test result is positive, secure the cap with the Security Seal, and send the cup to laboratory for confirmation testing.

